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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,049	11/13/2006	David Morritz De Kretser	19721	5961

23389 7590 08/28/2008

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,049	DE KRETSER ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

For examination purposes "use" claims are interpreted as a method of the first recited "use".

2. The following is noted:

A) Independent Claims 1-2 and 31 include a recitation of "modulating the inflammatory response"/"therapeutically and/or prophylatically treating a condition". Claim 1 further recites that modulating the functional activity of activin, wherein "upregulating activin" and "downregulating activin". These methods are mutually exclusive in that they reach opposing endpoints, and in that they employ structurally distinct agonists or antagonists to accomplish these mutually exclusive endpoints. Consequently, the claims have been limited to either a method of upregulating activin by contacting with an agonist of the activin, or a method of downregulation of activin by contacting with an antagonist of the activin, irrespective of the format of the claims.

B) There are three activin isoforms: activin A, AB and B ($\beta A\beta A$, $\beta A\beta B$ and $\beta B\beta B$) and two types of activin receptors: type I and Type II receptors.

C) Claims 5, 9, 10, 15, 17, 21-24, 30, 39, 46, 49-53, 59 and 60 are improper form: a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims1-20, 24-25, 30-49 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **upregulation** of activin functional activity achieved by introducing into a mammal a nucleic acid molecule encoding activin.

II. Claims1-20, 24-25, 30-49 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein

modulating is **upregulation** of activin functional activity achieved by introducing into a mammal the activin expression product.

III. Claims1-19, 21, 24-25, 30-48, 50 and 59, drawn to a method of modulating the inflammatory response /therapeutically and/or prophylactically treating a condition achieved by introducing into a mammal a *proteinaceous* molecule which modulates transcriptional and/or translational regulation of the activin gene.

IV. Claims1-19, 21, 24-25, 30-48, 50 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition achieved by introducing into a mammal a *non-proteinaceous* molecule which modulates transcriptional and/or translational regulation of the activin gene.

V. Claims 1-9, 22, 24-25, 30-48, 51 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **upregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an agonist of the activin expression product.

VI. Claims 1-19, 22, 24-25, 30-48, 51 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **upregulation** of activin functional activity, achieved by introducing a non-proteinaceous molecule which functions as an agonist of the activin expression product.

VII. Claims 1-19, 23-26, 30-48, 52-55 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *follistatin.*

VIII. Claims 1-19, 23-26, 30-48, 52-55 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *an agent that upregulates the levels of the α subunit of inhbin.*

IX. Claims 1-19, 23-26, 30-48, 52-55 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *inhbin.*

X. Claims 1-19, 23-26, 30-48, 52-55 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *an agent that upregulates the levels of βC.*

XI. Claims 1-19, 23-28, 30-48, 52-57 and 59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *an activin neutralizing antibody, wherein the antibody is* ***directed to the βA subunit of activin.***

XII. Claims 1-19, 23-27, 29-30-48, 52-56 and 58-59, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *an activin neutralizing antibody, wherein the antibody is* ***directed to the βB subunit of activin.***

XIII. Claims 1-19, 23-26, 30-48, 52-55, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a proteinaceous molecule which functions as an antagonist of the activin expression product, wherein the antagonist is *activin mutant.*

XIV. Claims 1-19, 23-26, 30-48, 52-55, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a non-proteinaceous molecule which functions as an antagonist of the activin expression, product, wherein the antagonist is an *agent that upregulates the levels of the α subunit of inhibin.*

XV. Claims 1-19, 23-26, 30-48, 52-55, drawn to a method of modulating the inflammatory response/therapeutically and/or prophylactically treating a condition, wherein modulating is **downregulation** of activin functional activity, achieved by introducing a non-proteinaceous molecule which functions as an antagonist of the activin expression, product, wherein the antagonist is an *agent that upregulates the levels of the βC.*

XVI. Claim 60, drawn to a pharmaceutical composition comprising the modulatory agent as hereinbefore defined and one or more pharmaceutical acceptable carriers. (**EASH agent is a separate GROUP**).

5. The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group XVI was found to have no special technical feature that defined the contribution over the prior art of US Pat. No. 5,545,616) (see entire document).

The '616 patent teaches the use of human follistatin or a humanized antibody to activin in a method of avoiding premature labor (see claims 1-8). The follistatin and anti-activin antibody must be in a pharmaceutical acceptable carrier for the *in vivo* use.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Group I-XV is elected, applicant is required to elect (i) a single specific condition/inflammatory response such as the one recited in claims 6-16 and 35-45; (ii) whether the inflammatory response is a) acute or b) chronic response recited in claims 10 and 15; (iii) the modulation is targeting a) activin A, b) activin AB or c) activin B. The activin isotypes are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints. The conditions/inflammatory responses species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any

claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on (571) 272-0878. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

August 27, 2008

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